

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date	7/28/01
Publication Date	7/28/01
Certifier	Monica Oliver

[Docket No. 01D-0281]

Medical Devices; A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures." This draft guidance is intended to assist the medical device industry and FDA staff in implementing a pilot premarket review program that may reduce some of the burden on manufacturers associated with current conflicting format and content requirements in different countries. The proposed pilot program will evaluate the utility of two documents created by the Global Harmonization Task Force (GHTF), Study Group 1 (SG1), entitled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" and "Essential Principles of Safety and Performance of Medical Devices" (Essential Principles). The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this draft guidance and the related GHTF documents by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for

Premarket Procedures” and related GHTF documents to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written or electronic comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is conducting a pilot premarket review program and is soliciting participation from the medical device industry. The pilot program is intended to evaluate the utility of a draft document that was prepared by the GHTF, SG1, to help harmonize the different requirements for premarket submissions in various countries. The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The purpose of the GHTF is to: (1) Encourage convergence in regulatory practices relating to ensuring the safety, effectiveness/performance, and quality of medical devices; (2) promote technological innovation; and (3) facilitate international trade. The GHTF Web site at: <http://www.ghrf.org> describes its organization, goals, and procedures. The GHTF draft document describes an internationally harmonized format and content for premarket submissions, e.g., premarket approval applications (PMAs) and 510(k) submissions, based on conformity to the Essential Principles document. The Essential Principles are a GHTF-derived list of both general and specific safety and performance recommendations for medical devices.

The announcement of the pilot premarket review program consists of the FDA draft guidance, which is the subject of this notice, and three related documents for comment appended to the FDA draft guidance: (1) A draft letter to the global medical device industry announcing the pilot program; (2) the draft STED document created by GHTF, SG1; and (3) the GHTF final document entitled "Essential Principles of Safety and Performance of Medical Devices."

The draft guidance document is intended to assist the medical device industry in completing a submission to FDA that uses the draft STED format and is also in accordance with U. S. requirements. The announcement letter describes specifics regarding the proposed pilot premarket program. The Essential Principles document is referenced in the draft STED document.

Four of the founding members of the GHTF are participating in the pilot program. They include the United States, Canada, Australia, and the European Union. Each of the participants will provide specific directions for implementing the pilot program within its jurisdiction.

The GHTF wants to assess the international utility of the draft STED document. Therefore, SG1 of the GHTF encourages manufacturers to prepare and submit, if submission is required, STEDs for the same device to as many of the four participating GHTF member countries as possible. SG1 also encourages manufacturers to try the draft STED format for different classes of devices that are candidates for the pilot program.

FDA intends to process premarket submissions in the draft GHTF harmonized format within statutory time limits and with review times comparable to other submissions for similar products. There will be no expedited review of submissions, unless the device merits such a process under current policies.

FDA plans to conduct the pilot program for 1 year. The pilot program will begin on the date of publication of the final FDA guidance document. FDA will assess how the pilot is proceeding during its course and may choose to decline receipt of additional submissions using the draft STED format in order to assess the initial experiences. At the end of the pilot, FDA and other GHTF participants will analyze the outcome to determine whether the draft STED

document is a viable alternative to current premarket submission procedures, and if the program should be continued or expanded. FDA will post on its Web site a report of the outcome of the pilot program.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on one possible way to evaluate and apply GHTF recommendations related to premarket submissions to FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document announcing the pilot is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

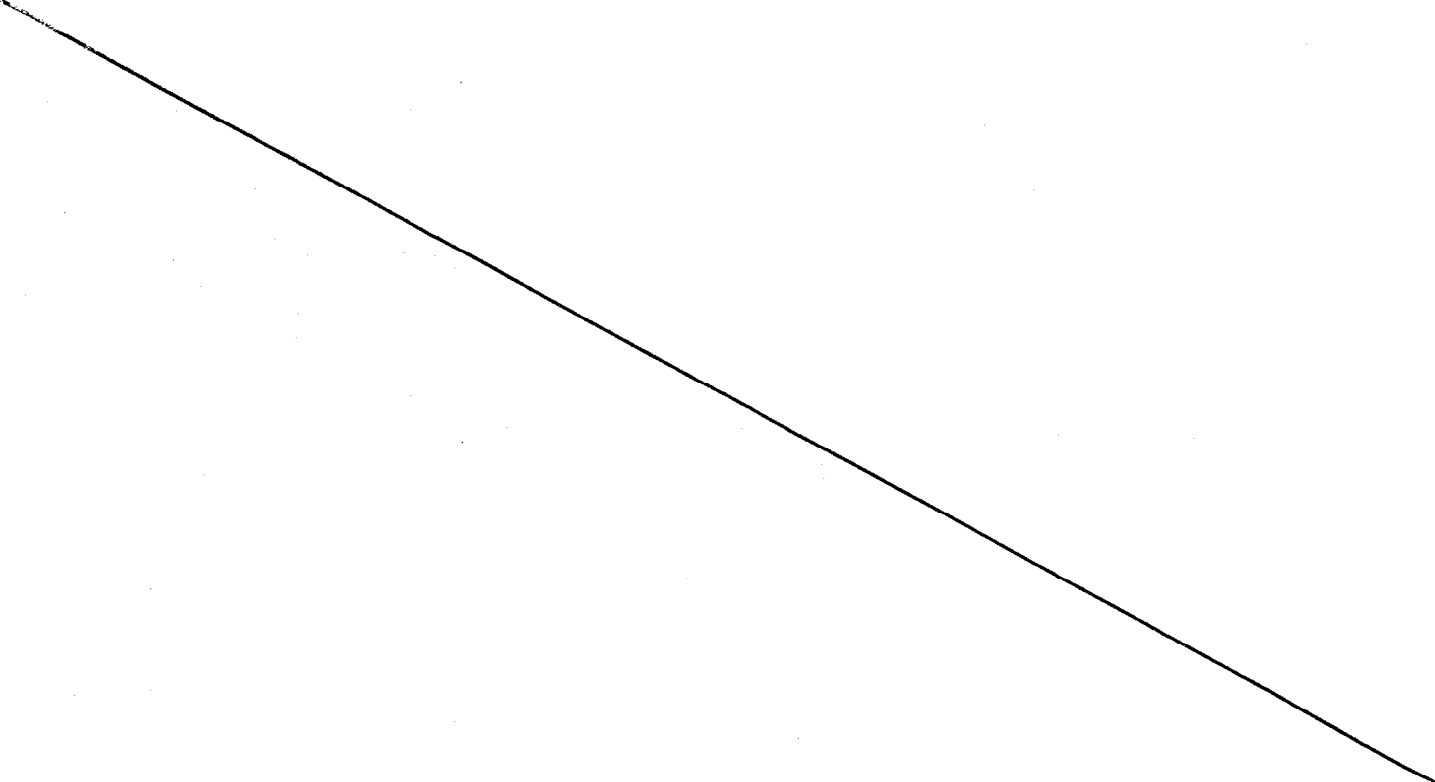
In order to receive a copy of the draft guidance entitled "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of

approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. Submit two copies of any comments, except that individuals may submit



one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/13/01
July 13, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Linda S. Kahan

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

Nomoni Oliver

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S